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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/307,640 09/16/94 FERGUSON

M MCNE, P0109
EXAMINER

ADAMS, D

ART UNIT PAPER NUMBER

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CLEVELAND OH 44115

18N1/1013

1816

DATE MAILED:

10/13/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-941 |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474.. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-20 are pending in the application
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-20 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☒ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☒ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

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15. Claims 1-20 are currently pending.

16. Claims 1, 3, 4, 6, 7, 12, 17, 18 and 20 have been amended.

5 17. This application does not contain an Abstract of the Disclosure as required by 37 C.F.R. § 1.72(b). An Abstract on a separate sheet is required.

10 18. Applicant is reminded of the proper content of an Abstract of the Disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains.

15 If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure.

20 If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement.

25 In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof.

30 If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

35 Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- 40 (4) if a mixture, its ingredients; and
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

45 19. Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts, compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the
50 class of alkyl benzene sulfonyl ureas, useful as oral anti-

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5 diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary. Complete revision of the content of the abstract is required on a separate sheet.

10 20. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119, the papers have been made of record in the file.

15 21. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

20 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

25 22. The specification is objected and claims 4 and 5 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and for failing to adequately teach how to make and/or use the invention, i.e. for failing to provide an enabling disclosure.

30 A) The specification does not define the anti-fibrotic agents. It appears from the specification that only those anti-fibrotic agents which inhibit the activity of a fibrotic agent will work in the claimed invention. Merely binding an agent with an antibody will have little effect if the antibody will not inhibit the agents activity. Applicant is invited to clarify this issue.

35 23. Claims 1-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

40 A) The claims would read much more clearly if Markush language is used. This would alleviate the need for terms such as "(s)" and "and/or".

45 B) The term "compositions" used in the preamble of claim 1 is unclear. Which specific composition is referred to in this claim?

50 C) The term "for example" is not appropriate in the recitation of the claimed invention.

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5 D) Claims 8-11 and 13 are objected to under 37 C.F.R. § 1.75(c) as being in improper form because they depend from a multiple dependent claim, claim 5. See M.P.E.P. § 608.01(n). Accordingly, claims 8-11 and 13 have not been further treated on the merits.

24. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

- 10 A person shall be entitled to a patent unless --
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- 15 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 20 25. Claims 1, 3, 6, 17, 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Geistlich et al. [WO 90/03810 (1990)]. Geistlich et al. teach delayed release compositions for wound healing. Such compounds are interspersed in a hydrogel. Geistlich et al. teach the preparation of the hydrogel
25 composition. See abstract and pages 1-4. Mere recitation of newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art. In re Best, 195 U.S.P.Q. 430, 433 (CCPA 1977). The composition of Geistlich et al. is the same as
30 that claimed. Thus, the Geistlich et al. composition inherently has the same properties as the composition claimed. The burden of proof is on applicant where rejection is based on inherency under 35 U.S.C. 102. Best, at 433.
- 35 26. Claims 1, 2, 6, 7, 12 and 14-20 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cerletti et al. [EP 0 433 225 (1990)]. Cerletti et al. teach a method for treating wounds using a TGF- β like protein. See page 5, lines 9-19. Cerletti et al. teach TGF- β like proteins refers to TGF- β_1 , TGF- β_2 , and TGF- β_3 .
40 See page 4, lines 54-56. Mere recitation of newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art. In re Best, 195 U.S.P.Q. 430, 433 (CCPA 1977). The composition of Geistlich et al. is the same as that claimed.
45 Thus, the Geistlich et al. composition inherently has the same properties as the composition claimed. The burden of proof is on applicant where rejection is based on inherency under 35 U.S.C. 102. Best, at 433.

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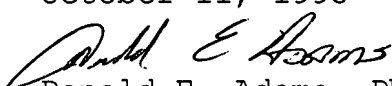
27. Claims 1, 4 and 5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ruoslahti et al. [WO 91/10727 (1991)]. Ruoslahti et al. teach a method of treating a pathology caused by a TGF- β regulated activity including fibrotic disease. See page 10, lines 25-35. Ruoslahti et al. teach anti-fibrotic agents. See page 24-27. Mere recitation of newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art. In re Best, 195 U.S.P.Q. 430, 433 (CCPA 1977). The composition of Geistlich et al. is the same as that claimed. Thus, the Geistlich et al. composition inherently has the same properties as the composition claimed. The burden of proof is on applicant where rejection is based on inherency under 35 U.S.C. 102. Best, at 433.

28. No claim allowed.

29. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4227.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donald E. Adams whose telephone number is (703) 308-0570. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Margaret Moskowitz Parr can be reached at (703) 308-2554. The fax phone number for Group 180 is (703) 305-3014 or (703) 308-4227. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

October 11, 1995


Donald E. Adams, Ph.D.
Primary Examiner
Group 1800